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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,208	07/09/2001	David Tsai	01-06-1685	9093

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EXAMINER

CELSA, BENNETT M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 04/21/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/902,208	Applicant(s) Tsai, David
Examiner Bennett Celsa	Art Unit 1639

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2-3

4) Interview Summary (PTO-413) Paper No(s). _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

Art Unit: 1639

DETAILED ACTION

Status of the Claims

Claims 1-9 are currently pending and under consideration.

NOTE: the location of the present application is ART UNIT 1639.

Priority

1. Applicant's claim for priority under 35 U.S.C. 120 of the present application which is a CIP of 09/414,136 is acknowledged. However, the 09/414,136 application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-9 of this application (e.g. fails to disclose or claim "supercharged fetuin" and method steps as presently claimed). Accordingly, for purposes of prior art the presently claimed invention is afforded the filing date of the present application (E.g. 7/9/01).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "supercharged zinc fetuin" in claims 1-19 is a relative term which renders the claim indefinite. The term "supercharged zinc fetuin" is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree (e.g. amount of zinc/fetuin

Art Unit: 1639

and/or necessary specific activity to be deemed sufficiently supercharged), and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. .

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1639

6. Claims 6-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Spiro, R.G. J. Biol. Chem. Oct. 1960 Vol. 235, no. 10 pages 2860-2869.

Present claims 6-9 are drawn to “product by process claims” which define the product by its method of making. See MPEP 2113 directed to “Product by Process Claims”. Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 173 USPQ 685, 688 (CCPA 1972).

Art Unit: 1639

The presently claimed invention is directed to “supercharged zinc fetuin” which is prepared by:

- a. incubating fetuin in sol’n with a chelating agent;
- b. isolating naked fetuin from step (a);
- c. incubating the naked fetuin in sol’n with zinc acetate; and
- d. isolating “supercharged zinc fetuin” from the sol’n in step c.

The Spiro article isolates a fetal bovine fetuin which comprises zinc which appears to be within the scope of the “super-charged zinc fetuin” presently claimed. E.g. see Spiro page 2862 and diagram 1.

In this regard, product-by-process claims are treated as product claims by the PTO; accordingly meeting the product fetuin structure anticipates a product-by-process claim. Other properties (if any) currently encompassed by the presently claimed invention would necessarily result from the same structure (e.g. “supercharged”). It is noted that the Examiner lacks the necessary facilities to make a comparison of the properties possessed by the prior art peptide against chemical properties as presently claimed.

Art Unit: 1639

7. Claims 6-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tsai et al. US Pat. No. 5,994,298 (11/99).

Present claims 6-9 are drawn to “product by process claims” which define the product by its method of making. See MPEP 2113 to “Product by Process Claims”. Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 173 USPQ 685, 688 (CCPA 1972).

The presently claimed invention is to “supercharged zinc fetuin” which is prepared by:

Art Unit: 1639

- a. incubating fetuin in sol'n with a chelating agent;
- b. isolating naked fetuin from step (a);
- c. incubating the naked fetuin in sol'n with zinc acetate; and
- d. isolating "supercharged zinc fetuin" from the sol'n in step c.

The Tsai et al. patent reference isolates (e.g. "modified Spiro method") a fetal bovine fetuin which comprises zinc and induces cancer cell apoptosis and thus appears to be within the scope of the "super-charged zinc fetuin" presently claimed. E.g. Tsai et al. at col. 16-18

In this regard, product-by-process claims are treated as product claims by the PTO; accordingly meeting the product fetuin structure anticipates a product-by-process claim. Other properties (if any) currently encompassed by the presently claimed invention would necessarily result from the same structure (e.g. "supercharged"). It is noted that the Examiner lacks the necessary facilities to make a comparison of the properties possessed by the prior art peptide against chemical properties as presently claimed.

Art Unit: 1639

8. Claims 6-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yu, PG Publication No. US /2003/0044400 A1 (March 6, 2003; effective filing date May 22, 2001).

Present claims 6-9 are drawn to “product by process claims” which define the product by its method of making. See MPEP 2113 to “Product by Process Claims”. Even though product - by process claims are limited by and defined by the process, determination of patentability is *based on the product itself*. The patentability of a product does not depend on its method of production. If the product in the product - by - process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe* , 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983). When the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product - by - process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown* , 173 USPQ 685, 688 (CCPA 1972).

Art Unit: 1639

The presently claimed invention is to “supercharged zinc fetuin” which is prepared by:

- a. incubating fetuin in sol’n with a chelating agent;
- b. isolating naked fetuin from step (a);
- c. incubating the naked fetuin in sol’n with zinc acetate; and
- d. isolating “supercharged zinc fetuin” from the sol’n in step c.

The Yu patent publication discloses “zinc-charged fetuin” which is apoptic to cancer cells made by the addition of zinc acetate following the isolation of bovine fetal fetuin purified by the modified Spiro method; which “zinc-charged fetuin” appears to be within the scope of the “supercharged zinc fetuin” presently claimed. E.g. see Yu at page 8.

In this regard, product-by-process claims are treated as product claims by the PTO; accordingly meeting the product fetuin structure anticipates a product-by-process claim. Other properties (if any) currently encompassed by the presently claimed invention would necessarily result from the same structure (e.g. “supercharged”). It is noted that the Examiner lacks the necessary facilities to make a comparison of the properties possessed by the prior art peptide against chemical properties as presently claimed.

Art Unit: 1639

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu, PG Publication No. US /2003/0044400 A1 (March 6, 2003; effective filing date May 22, 2001).

The presently claimed invention is to a method of obtaining “supercharged zinc fetuin” (and the product obtained) which is prepared by:

- a. incubating fetuin in sol’n with a chelating agent;
- b. isolating naked fetuin from step (a);
- c. incubating the naked fetuin in sol’n with zinc acetate; and
- d. isolating “supercharged zinc fetuin” from the sol’n in step c.

The Yu patent publication discloses “zinc-charged fetuin” which is apoptic to cancer cells made by the addition of zinc acetate following the isolation of bovine fetal fetuin purified by the modified Spiro method; which “zinc-charged fetuin” appears to be within the scope of the “supercharged zinc fetuin” presently claimed. E.g. see Yu at page 8. However, the Yu patent reference also teaches that commercial fetuin produced by Sigma by the Pederson method lacks apoptic activity due to the use of EDTA which deprives the metal ions bound to fetuin during the process of purification; and further discovered that Zinc is the critical ion necessary to apoptic activity (E.g. substitution of barium for zinc in the modified spiro abolished apoptic activity).

Accordingly, one of ordinary skill in the art in light of the Yu patent teaching would be motivated to form a “zinc charged/supercharged fetal fetuin” following the removal of other ions (including zinc) using a chelating agent, such as EDTA (forming a “naked fetuin”) by reacting zinc acetate as taught by Yu since Yu also teaches that zinc is critical toward obtaining the highest

Art Unit: 1639

degree of cancer cell apoptosis; and indeed obtains a “charged zinc fetuin” which is highly apoptic through the addition of zinc acetate..

It is noted that obtaining optimum amounts of fetuin, zinc acetate and chelating agent in solution is well within the skill of the art.

Thus, it would have been obvious to one of ordinary skill in the art obtain a naked fetuin (e.g. by removal of all ions using a chelating agent such as EDTA) and then recharge the fetuin solely with zinc (e.g by adding zinc acetate) in order to isolate a “(super)charged zinc fetuin” as presently claimed in light of the Yu patent publication reference which teaches the criticality of zinc ions which are absent from “naked fetuin” (e.g. following the addition of a chelating agent as in the Pederson method) and in its further teaching of the utilization of zinc acetate to isolate a “zinc-charged fetuin” which possesses strong apoptic activities.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

April 21, 2003

BENNETT CELSA
PRIMARY EXAMINER

